DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

d1688b

December 20, 1996

97-DAL-WL-09

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Neill Walsdorf, President
Mission Pharmacal Co., Inc.
10999 IH 10 West, Suite 1000
San Antonio, Texas 78230-1355

Dear Mr. Walsdorf,

During an inspection of your manufacturing facility located in Boerne, Texas conducted on October 17-18 and 22-24, 1996, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure to adequately validate manufacturing processes for your drug products, e.g. Theragesic Analgesic Cream, Super Quin-9 disinfectant, Prenate Ultra, Prenate 90, Hi-Nate 90, deionized water systems, equipment cleaning and drug reprocessing procedures. [21 CFR 211.110(a)]

2. Failure to implement an approved stability testing procedure for prescription drug products. [21 CFR 211.166(a)]

3. Failure to perform assay testing of the active ingredients for the drug product, Super Quin-9 Disinfectant. [21 CFR 211.165]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. We are aware that, even though this was the initial inspection of this facility, your firm has been advised about similar deviations found at other manufacturing sites under your control and authority. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations for all your facilities. Federal agencies are advised of the issuance of all warning letters

about drugs so that they may take this information into account when considering the awarding of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

We received your correspondence, dated October 29, 1996, on November 7, 1996, and have the following comments and questions. We agree with your decision to discontinue marketing Super Quin-9 until its regulatory status has been determined, however your letter failed to address the status of previously distributed product. As labeled, Super Quin-9 fits the definition of a drug and device. Please submit the following documents to this office 1) your proposed labeling changes for Super Quin-9; 2) all validation protocols referenced in your correspondence; and 3) the change request forms for the revised purified water procedures. The Stability Studies protocol and revised Tableting Data Sheet which you submitted appear satisfactory. The adequacy of your corrective actions will be evaluated during our next inspection.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Brenda C. Cox, Acting Compliance Officer, at the above letterhead address.

Sincerely yours,

Sylvia G. Yetts FOR

Joseph R. Baca
Dallas District Director